

REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

As an initial matter, it is noted that two different Official Actions were issued on March 16, 2006 for this application. The remarks below discuss the issues raised in both Official Actions.

To advance prosecution of this application and reduce the issues under consideration, Claims 1-10 have been canceled. Thus, the only claims currently pending in this application are Claims 11-20, with Claim 11 being the only independent claim.

Claim 11 recites a catheter comprising an observation portion used for observation of the inside of an organism, an observation lumen in which the observation portion is disposed and which extends in the direction of insertion into the organism, and first and second guide wire lumens. The first guide wire lumen is disposed substantially parallel to the observation lumen, and the proximal end of the first guide wire lumen is disposed on the distal end side in the insertion direction in relation to the observation portion and through which a guide wire is passed. The second guide wire lumen is disposed on an extension line of the first guide wire lumen, and the distal end of the second guide wire lumen is disposed on the proximal end side in the insertion direction in relation to the observation portion and through which the guide wire is passed. The proximal end and the distal end of the first guide wire lumen each possess an opening, and the proximal end and the distal end of the second guide wire lumen each possess an opening. The opening at the proximal end of the first guide wire lumen and the opening at the distal end of the

second guide wire lumen are spaced apart from one another such that when a guide wire is positioned in both the first guide wire lumen and the second guide wire lumen a portion of the guide wire is located exterior of the sheath

One of the Official Actions sets forth a rejection of independent Claim 11 based on the disclosure in U.S. Patent No. 5,312,427 to *Shturman*. That rejection is respectfully traversed for the following reasons.

Shturman discloses a device for performing an atherectomy. The disclosed device includes an elongated catheter 20 provided with a pair of lumens 24, 26. The lumen 24 is adapted to receive a guide wire 90 while the other lumen 26 is adapted to receive a flexible drive shaft 50 that possesses a lumen 56. An abrasive burr 40 is carried at the distal end of the flexible drive shaft 50 and is provided with a central lumen 46. A positioning wire 70 is disposed in the lumen 56 of the drive shaft 50 and includes a distal end 74 slidably secured about the guide wire 90.

It is understood from the comments in the Official Action that the lumen 24 in the catheter 20 of *Shturman* corresponds to the claimed first guide wire lumen while the opening defined within the distal end 74 of the positioning wire 70 corresponds to the claimed second guide wire lumen.

One way in which the catheter at issue here distinguishes over the arrangement disclosed in *Shturman* is that the first guide wire lumen and the second guide wire lumen are both disposed on the sheath. Claim 11 has been amended to recite this distinction. Quite clearly, this is not the case with the device disclosed in *Shturman* as the opening within the distal end 74 of the positioning wire 70 (i.e., the second guide wire lumen) is not disposed on the sheath 20. It is thus respectfully

submitted that the anticipatory rejection of independent Claim 11 based on the disclosure in *Shturman* is no longer appropriate and should be withdrawn.

One of the Official Actions also sets forth a rejection of independent Claim 11 based on the disclosure in U.S. Patent No. 5,976,093 to *Jang* in view of the disclosure in *Shturman*. That rejection is also respectfully traversed.

Jang discloses an ultrasonic imaging catheter comprising a catheter body 202 having a distal region and a proximal region. The distal region includes a single lumen 212, while the proximal region includes several lumens 214, 216, 218, one of which accommodates a guide wire 220 as illustrated in Fig. 14. As understood from the Official Action, the lumen 212 disclosed in *Jang* is considered to correspond to the claimed first guide wire lumen while the lumen 216 disclosed in *Jang* is interpreted to correspond to the claimed second guide wire lumen.

Independent Claim 11 has been amended to recite that the proximal end of the first guide wire lumen and the distal end of the second guide wire lumen are positioned relative to one another to permit a guide wire extending between the proximal end of the first guide wire lumen and the distal end of the second guide wire lumen to extend exterior of the sheath. In *Jang*, the proximal end of the first guide wire lumen 212 and the distal end of the second guide wire lumen 216 are not positioned relative to one another to permit a guide wire extending between the proximal end of the first guide wire lumen 212 and the distal end of the second guide wire lumen 216 to extend **exterior** of the sheath.

The Official Action indicates that *Shturman* discloses spaced apart guide wire lumens having openings such that an extending guide wire is outside the catheter. However, a careful reading of the disclosure in *Shturman* reveals that the particular

arrangement disclosed in *Shturman* has no application to the catheter disclosed in *Jang*.

As discussed in the first full paragraph of column 10 of *Shturman*, the disclosed device is specifically adapted to remove an atherosclerotic lesion or atheroma 12 from an artery 10 as illustrated in Figs. 2-10. The positioning wire 70 with its distal end 74 engaging the guide wire 90 is provided for purposes of facilitating positioning of the burr 40 used to remove the lesion from the artery. Because the catheter disclosed in *Jang* is not intended to remove a lesion from an artery through use of a burr that is connected to a flexible drive shaft, there would have been no reason to employ *Shturman's* disclosure of the distal end 74 of a positioning wire 70 engaging a guide wire. Stated differently, the reason *Shturman* discloses extending the guide wire 90 through the lumen 24 of the catheter 20 and through an opening (second guide wire lumen) in the distal end 74 of the positioning wire 70 has no application in the context of the catheter disclosed in *Jang*. Absent *Shturman's* objective of removing a lesion from an artery, an objective with which *Jang* is completely unconcerned, one of ordinary skill in the art would not have been motivated to utilize the disclosure in *Shturman* to modify the catheter disclosed in *Jang* for purposes of including first and second guide wire lumens in which the proximal end of the first guide wire lumen and the distal end of the of the second guide wire lumen are positioned relative to one another to permit a guide wire extending between the proximal end of the first guide wire lumen and the distal end of the second guide-wire lumen to extend exterior of the sheath.

Even if one were somehow motivated to incorporate the disclosure in *Shturman* into the catheter disclosed in *Jang*, as pointed out above, *Shturman* does

not disclose first and second guide wire lumens that are both disposed on the sheath. It is thus respectfully submitted that a combination of the disclosure in *Jang* and *Shturman* would not have motivated one of ordinary skill in the art to do that which is recited in independent Claim 11 as the invention.

One of the Official Actions issued on March 16, 2006 also sets forth a rejection of independent Claim 11 based on the disclosure in U.S. Patent No. 5,024,234 to *Leary et al.* in view of the disclosure in U.S. Patent No. 5,468,225 to *Tierstein*.

Leary et al. discloses a catheter having a first guide wire lumen 112 and a second guide wire lumen 116 through which a guide wire 114 can pass. When the guide wire 114 is inserted in the lumens 112, 116, a part of the guide wire is located exterior of the catheter.

The catheter disclosed in *Tierstein* includes a distal guide wire lumen 44 and a proximal guide wire lumen 46 for receiving a guide wire 30. As the guide wire 30 is inserted into the distal guide wire lumen 44 and the proximal guide wire lumen 46, a part of the guide wire is located exterior of the catheter.

However, in both *Leary et al.* and *Tierstein*, the two guide wire lumens are positioned so that the portion of the guide wire extending exterior of the catheter between the proximal end of the first (distal) guide wire lumen and the distal end of the second (proximal) guide wire lumen is bent (i.e., does not extend along a straight line) in the manner illustrated in Fig. 11 of *Leary et al.* and Fig. 3 of *Tierstein*. In contrast, as now set forth in independent Claim 11, the first and second guide wire lumens are positioned so that a guide wire extending between the proximal end of

the first guide wire lumen and the distal end of the second guide wire lumen extends exterior of the sheath in a **straight line without bending**.

It is thus respectfully submitted that a combination of the disclosures in *Leary et al.* and *Tierstein* would not have directed one to provide a catheter having the construction recited in independent Claim 11.

Claims 12-20 depend from Claim 11 and recite further distinguishing features and characteristics associated with the catheter at issue here. As these dependent claims are allowable at least by virtue of their dependence from allowable independent Claim 11, such additional distinguishing aspects of the claimed catheter are not discussed in detail at this time.

For at least the reasons set forth above, withdrawal of the rejections of record and allowance of this application are earnestly solicited.

For at least the reasons stated above, it is requested that all the rejections be withdrawn and that this application be allowed in a timely manner.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

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